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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,894	05/13/2005	Xiangyin Kong	186660/US	4722

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EXAMINER	
SHAFER, SHULAMITH H	
ART UNIT	**PAPER NUMBER**
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,894	KONG ET AL.	
	Examiner	Art Unit	
	Shulamith H. Shafer, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-18,20 and 25-33* is/are pending in the application.

4a) Of the above claim(s) *27* is/are withdrawn from consideration.

5)☒ Claim(s) *13-18,25 and 26* is/are allowed.

6)☒ Claim(s) *20 and 28-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/23/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Status of Application, Amendments, And/Or Claims:

Restriction Requirement:

Applicant's election, with traverse of Group II, claims 13-18, drawn RhoR polynucleotide, in the reply filed on 6 June 2007, in response to Office Action of 6 March 2007 is acknowledged. The grounds for the traversal are that art cited to indicate lack of same or corresponding special technical features, Strausberg et al. (2002 PNAS 99:16899-16903), was published later that Applicant's priority date, the date of priority document China 02 145253.9 (13 November 2002). Therefore, claims 13-18, 20 and new claims 25-33 are linked and relate to a single general inventive concept under PCT Rule 13.1 and should all be examined together. Applicant's arguments have been found to be persuasive in part. The first claimed invention in the originally amended listing of claims (submitted 13 May 2005) was drawn to the polypeptide of SEQ ID NO:2. In compliance with CFR 1.475, the first claimed product (polypeptide), a process adapted for manufacture of said product (recombinant method using host cells, vector and DNA encoding said polypeptide) and a use of the said product (method for treating baldness) will be under consideration.

Claims 1-10, 19, 21-24 have been canceled. Claim 20 has been amended and the amendment made of record. Claims 25-33 have been newly presented and made of record.

Claims 13-18, 20, 25, 26, and 28-33 are under consideration. The restriction requirement between these claims and Claim 27, drawn to kit, is maintained.

This requirement is made **FINAL**.

In summary, Claims 13-18, 20, 25-33 are pending in the instant application. Claim 27 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 13-18, 20, 25, 26 and 28-33 are under consideration.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in China on 13 November 2002. Receipt is acknowledged of certified copy and certified translation of China 02145253, which papers have been placed of record in the file. Therefore, benefit of the foreign priority filing date, 13 November 2002, is granted.

Information Disclosure Statement:

Duplicate copies of the Information Disclosure statements (IDS) were submitted on 23 January 2006. Only one of the copies has been considered and signed. Duplicate references have been lined through.

Objections

The specification is objected to because it contains numerous typographical, spelling and grammatical errors. Examples of some errors are found on: page 2, line 31, page 7, line 36, page 11, line 24, page 12, line 11. Appropriate correction is required.

Rejections

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20, 28-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is vague and indefinite in reciting "efficient amount of the polypeptide...". It is unclear what the term "efficient", which is generally defined as performing or functioning effectively with a minimum of waste, expense or unnecessary effort, indicates within the context of the claim. Furthermore, if applicant intends to recite "a safe and effective amount of the polypeptide", it is unclear for what purpose the amount of polypeptide is to be safe and effective.

Claims 28, 29, 31 and 32 are vague and indefinite in reciting "Rhor polypeptide". The claims should refer to a sequence presented in the sequence listing. While the name itself may have some notion of the activity of the protein, there is nothing in the claim that distinctly identifies the protein. Others in the field may isolate the same protein and give it an entirely different name or give the same name to a different protein. Applicant should particularly point out definitive characteristics associated with the protein. Describing biochemical molecules by a particular name given to the protein by various workers in the field fails to distinctly identify what the protein is. Thus "Rhor polypeptide" is not sufficient to identify the claimed invention, and one of skill in the art would not be able to determine what molecules are encompassed.

Additionally, claim 28 is vague and indefinite in reciting "a mammal Rhor polypeptide". Since, by definition, only mammals have hair, express a baldness associated polypeptide, and suffer from baldness, it is unclear what "a mammal Rhor polypeptide" would encompass.

Claim 31 is an incomplete method claim. To be complete, a method claim must state a goal in the preamble of the claim, and conclude having achieved that goal. Claim 31 is directed to a method of treating baldness in a mammal. However, the method steps, as recited, are insufficient to accomplish the goal stated in the preamble. The method steps recite administration of a polypeptide. Thus, it is unclear if carrying out the method steps would result in accomplishing the goal set forth in the preamble. Additionally the claim is vague and indefinite in reciting "a mammal animal". It is unclear what type of organism applicant intends to treat. It is suggested that claim be amended to read, for example, "in a mammal". Furthermore the claim concludes by reciting

"subject in need of." It is unclear what said subject is in need of. It is suggested that claim be amended to read, for example, "in need thereof".

Claims 30, 32 and 33 are included in this rejection as dependent from rejected claims.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20, and 28-33 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims: Claim 20 is drawn to a composition comprising a safe and "efficient" amount of polypeptide of SEQ ID NO:2; Claim 28 is drawn to preparing a medicine comprising a Rhor polypeptide. For purposes of enablement analysis, both claims (and claims 29, and 30 which depend from claim 28) will be interpreted as drawn to a medicament for the treatment of baldness comprising the polypeptide of SEQ ID NO:2. Claims 31-33 are drawn to a method of treating baldness comprising administration of a polypeptide of SEQ ID NO:2. Thus, the claims are broadly drawn to a medicament and

method for treating baldness of any etiology comprising administration of a polypeptide of SEQ ID NO:2.

The teachings of the specification: The disclosure teaches a gene, which Applicant has identified as Rhor, wherein mutations of said gene is associated with baldness [paragraph 0021 of PGPUB 20060039884, the PGPUB of the instant application]. The Rhor mutation was identified in "hairless" Balb/c mice; heterozygous mice exhibit sparse hair, while homozygotes are hairless [pagragraph 0081]. DNA encoding the mutant protein comprises a 230 bp deletion in the genomic sequence of DNA encoding the wild-type protein [paragraph 0092]. The specification teaches "The Rhor polypeptide can be directly used for curing disorders, e.g., baldness. The Rhor protein can be administrated in combination with other medicaments used for treating baldness" [paragraph 0067]. Thus, the specification envisions administering the Rhor polypeptide (SEQ ID NO:2) as a treatment for the symptom of baldness due to any, nonspecified cause.

Working examples: There are no examples, working or prophetic, directed to administration of a polypeptide of SEQ ID NO:2 for the treatment of baldness.

The state of the art:

With regards to treatment of baldness:

The art teaches that there are many causes of hair loss or baldness. Springer et al (2003. American Family Phys. 68:93-102) teaches that among the common forms of hair loss are androgenetic alopecia, syphilis, trichotillomania, alopecia universalis, telogen effluvium, toxic exposure, chemotherapy, metabolic derangements, alopecia totalis, alopecia areata, tinea capitis, traction alopecia and cicatricial alopecia (page 95, Figure 1). Thus, one would not be able to predict that administration of a polypeptide of SEQ ID NO:2 would be able to treat individuals suffering from hair loss of any etiology. At best, administration of a polypeptide of SEQ ID NO:2 may be useful in treating individuals expressing a mutated form of the protein.

With regards to administration of polypeptides as pharmaceutical therapies:

It is well known in the art that the development and administration of pharmaceutical therapies, particularly therapies comprising administration of

polypeptides are unpredictable (see for example, Goodman and Gilman, 10th edition, McGraw-Hill, 2001, page 3-29) for the following reasons: (1) the peptide(s) or protein may be inactivated before producing an effect, ie such as proteolytic degradation, immunological inactivation or due to inherently short half-life of the peptide or protein; (2) the peptide(s) may not reach the target area, ie the peptide(s) or protein may not be able to cross the mucosa or may be adsorbed by fluids, cells and tissues where the peptide(s) or protein has no effect (3) other functional properties, known or unknown, may make the protein unsuitable for in vivo therapeutic use, ie such as adverse side effects prohibitive to the use of such treatment. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO BD. APP & Inter., 1992). Thus, undue experimentation on the part of the artisan would be required to use the methods of the instant invention to deliver a therapeutic polypeptide to an appropriate target in order to treat baldness.

Due to the large quantity of experimentation necessary to determine which of the many types of baldness would be treatable by the composition and methods of the instant invention, the lack of direction/guidance presented in the specification regarding same, the absence of sufficient working examples directed to same, the complex nature of the invention, the state of the prior art establishing that baldness has many diverse causes and the unpredictable of pharmaceutical therapies comprising administration of polypeptides, and the breadth of the claims which fail to recite any limitations as to the type and etiology of baldness to be treated, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

Prior art made of record:

The following prior art is made of record and not relied upon is considered pertinent to applicant's disclosure. Lal et al. (WO2003027228-A2, filed 16 July 2002) teach a polypeptide (SEQ ID NO:3), identified as REMAP protein #3, which is 92.1% identical to SEQ ID NO:2, the polypeptide of the instant invention (see enclosed alignment). However, the reference does not anticipate or suggest making changes in

the amino acid sequence to arrive at the amino acid sequence of SEQ ID NO:2. Lal et al. (PCT US02/22833, filing date 16 July 2002, the International Application of WO 03/027228) teaches a nucleic acid sequence that is 78.7% identical to nucleotides 1-2484 (SEQ ID NO:26) of the nucleotide sequence of SEQ ID NO:1 (see enclosed alignment). However, the reference does not anticipate or suggest making changes in the nucleic acid sequence to arrive at the nucleic acid sequence of SEQ ID NO:1.

Conclusion:

Claims 20, and 28-33 are rejected.

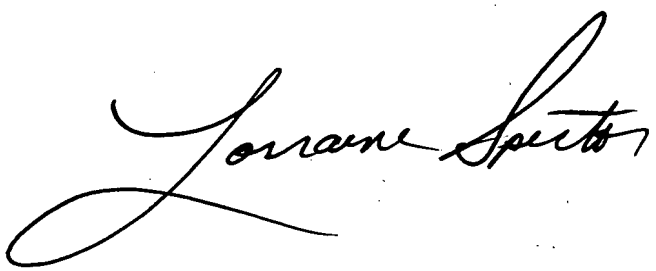
Claims 13-18, 25 and 26 are allowable. As discussed above, the prior art teaches an amino acid sequence that is 92.1% identical to the amino acid sequence of SEQ ID NO:2 and a nucleic acid sequence that is 78.7% identical to the nucleic acid sequence of SEQ ID NO:1. However, the prior art teachings do not anticipate or suggest making changes in the amino acid sequence or nucleic acid sequence to arrive at the sequences of the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shulamith H. Shafer, Ph.D. whose telephone number is 571-272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SHS



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